



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/922,013	08/03/2001	Mark Rutenberg	1373.016	1064

7590

01/31/2002

Peter L. Berger, Esq.  
LEVISOHN, LERNER, BERGER & LANGSAM  
Suite 2400  
757 Third Avenue  
New York, NY 10017

EXAMINER

BEISNER, WILLIAM H

ART UNIT

PAPER NUMBER

1744

DATE MAILED: 01/31/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

SN

## Office Action Summary

Application No.

09/922,013

Applicant(s)

RUTENBERG ET AL.

Examiner

William H. Beisner

Art Unit

1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 December 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 1-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

Art Unit: 1744

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of Group V in Paper No. 3 is acknowledged. The traversal is on the ground(s) that the claims of Group III are related to Group V and should be examined together. This is not found persuasive because the inventions of Group III and Group V are related as process and apparatus for its practice. A restriction is proper if the related inventions are distinct. In this case it has been shown that the method can be practiced by hand or by a system which does not include a computer.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 3.

### ***Drawings***

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the system must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 16-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 16-23 are drawn to a “system to detect cancerous and precancerous cells”. The body of the claims merely recite a computer. In the absence for further positively recited structural elements, it is not clear how the computer structure is capable of performing all of the recited intended functions of the claimed system.

In claims 17 and 23, it is not clear how the language of this claim further limits the structure of the device recited in claim 16?

In claims 19, 21 and 22, how does this language further limit the structure of the previous claim if the ploidy quantization is performed by a pathologist?

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 1744

7. Claims 16-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Rutenberg et al.(US 5,740,270).

The reference of Rutenberg et al. discloses a system which is capable of detecting cancerous and precancerous cells in a cell population which includes a computer (20) which includes a primary classifier and secondary classifier which identify individual cells for atypicality in terms of cell morphology and cytometry. After the cells are identified and locations stored in the computer, the system is able to select suspect cells for further analysis, tertiary classification, including manual classification (See column 4, lines 39-55; column 5, lines 5-7; and column 8, lines 35-60). Note while the instant claims recite limitations involving DNA ploidy quantization, the instant claims do not require any positively recited structure limitations for providing this intend function. It appears that the analysis is performed manually by a pathologist. The system of Rutenberg et al. is capable of identifying the suspect cells as is required of the instant claims. Additionally note the reference of Rutenberg et al. also discloses that the disclosed system is capable of DNA ploidy analysis and molecular detection methods (See column 14, lines 15-40).

### *Conclusion*

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The following prior art references are cited as prior art which pertains to image analysis systems for detecting cancerous or precancerous cells:

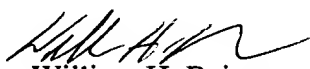
Art Unit: 1744

Bacus (US 5,526,258); Bacus et al.(US 5,541,064); Doerrer et al.(US 5,889,880); Boon et al.(US 5,939,278); Lee et al.(US 6,137,899); Alberts et al.(US 6,204,064); Eisen et al.(US 6,284,482); and Eisen et al.(US 6,297,044).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 703-308-4006. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:40am to 4:10pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Warden can be reached on 703-308-2920. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

  
William H. Beisner  
Primary Examiner  
Art Unit 1744

WHB  
January 28, 2002